

AMENDMENTS TO THE CLAIMS

1-9. (Canceled)

10. (Currently Amended) A process for preparing ~~[[recrystallized]]~~ randomly-ordered crystal agglomerates comprising an alkali metal clavulanate salt, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded, which comprises contacting a solution or suspension of alkali metal clavulanate salt in a solvent or mixture of solvents with one or more anti-solvents under stirring~~[[stirring a clavulanate in a liquid phase]]~~.

11. (Canceled)

12. (Currently Amended) A process according to claim ~~[[11]]~~ 10, wherein the ratio of the weight of the ~~[[solvent]]~~ solution containing β -lactam the clavulanate salt to the anti-solvent is about 0.05 to 10 wt.%.

13. (Currently Amended) A process according to claim ~~[[11]]~~ 10, wherein the solvent is ~~selected from the group consisting of~~ water, ethanol, or a mixture thereof, wherein water is present in said mixture.

14. (Currently Amended) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture ~~[[of these anti-solvents]]~~thereof, optionally containing water.

15. (Canceled)

16. (Previously Presented) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Previously Presented) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (Previously Presented) A process according to claim 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Previously Presented) A process according to claim 18, wherein the agglomerates have an average particle size between about 1 μm and 1500 μm .

20. (Currently Amended) A process according to claim [[11]] 10, wherein the process comprises dissolving [[one or more β -lactams]]the alkali metal clavulanate salt in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21-26. (Canceled)

27. (Previously Presented) A process according to claim 19, wherein the agglomerates have an average particle size about 100 μm .

28. (Previously Presented) A process according to claim 19, wherein the agglomerates have an average particle size about 1000 μm .

29. (Previously Presented) A process according to claim 10, wherein the agglomerates have a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (canceled)

31. (Previously Presented) A process according to claim 10, wherein the agglomerates have a Carr index compressibility between about 10 % and 40 %.

32. (Currently Amended) A process according to claim 10, wherein said alkali metal clavulanate [[comprises a clavulanate]]salt is potassium clavulanate.

33. (canceled)

34. (Currently Amended) A process according to claim[[33]] 32, wherein the agglomerates further comprise amoxicillin.

35. (Previously Presented) A process according to claim 10, wherein the agglomerates optionally contain one or more excipients.

36. (Previously Presented) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

37. (Currently Amended) An agglomerate of randomly-ordered crystals of an alkali metal clavulanate[[s]] salt having a Carr index compressibility, ~~wherein said agglomerate has a bulk density of between about [[0.2g/mL and 0.6 g/mL]]10% and 40%~~, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

38. (canceled)

39. (Previously Presented) The agglomerate of claim 37, further comprising amoxillin.

40. (Previously Presented) The agglomerate of claim 37, further comprising one or more excipients.

41. (Previously Presented) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (Previously Presented) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (Previously Presented) The agglomerate of claim 42, wherein said agglomerates has an average particle size of about 100 μm .

44. (Previously Presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μm .

45. (canceled)

46. (Currently Amended) The agglomerate of claim 37, wherein said alkali metal clavulanate[[s-comprise]] salt is potassium clavulanate.

47. (Previously Presented) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (Previously Presented) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (Previously Presented) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (Previously Presented) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.

51. (New) The agglomerate of claim 37, wherein said agglomerate has a loose bulk density of between about 0.2 g/mL and 0.6 g/mL.

52. (New) The agglomerate of claim 37, wherein said agglomerate have a weight percentage between 0-10% of non-agglomerates.

53. (New) The process of claim 10, wherein said agglomerates have a weight percentage between 0-10% of non-agglomerates.

54. (New) The process of claim 10, wherein the solvent is aqueous acetone.